

**SUPPORTING STATEMENT FOR AN
INFORMATION COLLECTION REQUEST**

1. IDENTIFICATION OF THE INFORMATION COLLECTION

1(a). Title of the Information Collection

**RECORDKEEPING REQUIREMENTS FOR CERTIFIED APPLICATORS
USING 1080 COLLARS FOR LIVESTOCK PROTECTION**

OMB NO. 2070-0074

EPA NO. 1249.07

1(b). Short Characterization/Abstract

This information collection activity will enable the Environmental Protection Agency (EPA, the Agency) to obtain the information needed to track the use of registered 1080 collars and the record keeping requirements imposed by an administrative judge in October 1982 and confirmed by the Agency in 1983. This ICR affects approximately 50 to 75 Certified Pesticide Applicators, who utilize 1080 toxic collars for livestock protection. Four states (Montana, New Mexico, South Dakota, and Wyoming) monitor the program, and five registrants are required to keep records of: a) number of collars purchased; b) number of collars placed on livestock; c) number of collars punctured or ruptured; d) apparent cause of puncture or rupture; e) number of collars lost or unrecovered; f) number of collars in use and in storage; and g) location and species data on each animal poisoned as an apparent result of the toxic collar.

Applicators maintain records, and the registrants/lead agencies do monitoring studies and submit the reports. These records are monitored by either the: a) state lead agencies; b) EPA regional offices; or c) the registrants. EPA receives annual monitoring reports from registrants or State lead agencies.

2. NEED FOR AND USE OF THE COLLECTION

2(a). Need/Authority for the Collection

The Administrator of the EPA banned all predator uses of Sodium Monofluoroacetate (Compound 1080) in 1972. In 1981 and 1982, EPA received several applications to register 1080 in a new delivery mechanism, the toxic collar. Following extensive public hearings in 1982, EPA's Administrative Law Judge Nissen declared, on October 22, 1982, that the Agency could register the collar, with certain specific use restrictions, after going through the normal registration process. The Administrative Law Judge included restrictions and recordkeeping requirements in Attachment C of his initial decision.

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On October 31, 1983, then EPA Assistant Administrator Lee M. Thomas affirmed Judge Nissen's initial decision, including the use restrictions and recordkeeping requirements.

2(b). Practical Utility/Users of the Data

As a condition of registration, EPA has required submission of annual reports monitoring use of all of Livestock Protection Collar products. Depending upon the product, the registrant or the State lead agency for pesticide regulation is designated as being responsible for annual monitoring report. The requirement to submit reports is imposed for at least the first four years of the collars' use under the registration. Factors affecting the extension of requirements to submit annual reports include: 1) quality of reports submitted previously; 2) results of collar use (in terms of numbers punctured by coyotes, numbers punctured by other causes, numbers lost, nontarget poisonings, etc.); and 3) frequency and nature of violations reported. In 1992, the requirement to submit annual monitoring reports was dropped for one Livestock Protection Collar product. EPA reviews the annual reports to ensure compliance with the 1982 Administrative Law decision.

3. NONDUPLICATION, CONSULTATIONS, AND OTHER COLLECTION CRITERIA

3(a). Nonduplication

The processes described above for recordkeeping, reporting nontarget exposure incidents, and submitting monitoring reports are not duplicative of any other known information collection requirement. This information would not be compiled or reported but for these special requirements for Livestock Protection Collars. While it is true that certain information on collar production may be required by agencies that prepare monitoring reports, this information would not, in the main, be duplicative of the confidential production reports that all pesticide registrants must file. The reports for the collar are limited to one specific, heavily regulated type of product. This type of information may not, in all cases, be available to the state lead agencies but for the specific reporting requirements that they impose upon registrants of livestock protection collars.

3(b). Consultations

As the recordkeeping requirements for certified Livestock Protection Collar users and collar registrants were imposed through the legal system, consultations were not conducted in connection with whether these activities would be required.

Prior to the initial registration of the Livestock Protection Collar, the EPA met in Dallas, Texas, with individuals representing many state and federal agencies to discuss labeling, certification, and registration. From this meeting, and subsequent discussions with these parties, the registrant of the first Livestock Protection Collar registration, and the concept of the monitoring study was developed. The registrant accepted the need for this study as a condition of registration. Subsequent registrants have done the same. The initial registrant, a federal agency, acted in behalf of other parties seeking registrations. Since this registrant elected not to use its own product, this registrant did not have to file any monitoring reports. That registration was transferred to another federal agency, which eventually used its own collars, and filed monitoring

reports in 1996, 1997, and 1998.

3(c). Effects of Less Frequent Collection

Annual monitoring reports are the only items pertaining to collars for which the EPA requires scheduled submissions. Longer intervals between submissions would make the EPA's responses to the reports less timely and increase the amount of time that would be needed to prepare each individual report. Reports submitted to date have consisted either of several pages of text, followed by several pages of tables or several pages of text and attachments. Data collection and table preparation appear to be the major burdens associated with monitoring reports.

3(d). General Guidelines

Requiring monitoring reports to be submitted once a year does not conflict with the general guidelines for data requesters. The required reporting of nontarget incidents, in practice, has not generated any rate of submissions that could be construed as being in violation of these general guidelines. The need for such incidents to be reported rapidly is clear, however. As discussed above, the reporting requirements for small entities have been limited as much as is legally and responsibly possible.

3(e). Confidentiality

Health and safety data submitted by registrants under FIFRA are considered by EPA to contain no confidential business information (CBI).

If, however, registrants submit data that relates to trade secrets or commercial or financial information, such information is protected from disclosure under Section 10 of FIFRA. Such data submitted to the EPA are handled strictly in accordance with provisions of the FIFRA Confidential Business Security Manual. This manual contains instructions relative to all contact with confidential documents, including: responsibilities of the EPA employees; physical security measures; CBI copying and destruction procedures; transfer of CBI materials within the EPA to contractors or other government offices; computer security; CBI typing procedures; and procedures internal to EPA. The manual dictates that all CBI must be marked or flagged as such, all CBI must be kept in secure (double-locked) areas, and all CBI intended to be destroyed must be cleared by a Document Control Officer and shredded.

3(f). Sensitive Questions

No information of a sensitive or private nature is requested in conjunction with this information collection activity. Further, this information collection activity complies with the provisions of the Privacy Act of 1974 and OMB Circular A-108.

4. THE RESPONDENTS AND THE INFORMATION REQUESTED

4(a). Respondents/NAICS Codes

The North American Industrial Classification System codes assigned to the businesses and other institutions participating in this program are **325320** (Pesticide and other Agricultural Chemical Manufacturing) and **9241** (Administration of Environmental Quality Control Programs).

4(b). Information Requested

(i) Data Items, Including Record Keeping Requirements

The data that certified Livestock Protection Collar applicators are required to record and maintain were outlined in the Initial Decision of the Administrative Law Judge in the 1080 Predicide Hearings. This decision was upheld and amplified in the Final Decision rendered by Lee Thomas, acting for then EPA Administrator William Ruckelshaus. Administrator Ruckelshaus recused himself from the decision due to his earlier involvement in the 1972 decision, leading to the cancellation of predacidal uses of Compound 1080. These requirements are stipulated in "USE RESTRICTION 5" in the technical bulletin that is part of the labeling for all Livestock Protection Collar products registered as pesticides in the United States. USE RESTRICTION 5, from a typical technical bulletin, reads as follows:

"Each applicator shall keep records dealing with the use of Livestock Protection Collars and the results of such use. Records shall be maintained in accordance with appropriate State or Federal regulations but for not less than two years following disposal or loss of collars. Such records shall include, but need not be limited to:

- (a) The number of collars attached on livestock.
- (b) The pasture(s) where collared livestock were placed.
- (c) The dates of each attachment, inspection, and removal.
- (d) The number and locations of livestock found with ruptured or punctured collars and the apparent cause of the damage.
- (e) The number, dates, and approximate location of all collars lost.
- (f) The species, locations, and dates of all suspected poisonings of humans, domestic animals or non-target wild animals resulting from collar use."

USE RESTRICTION 6, from the same typical technical bulletin, requires that "suspected" poisonings of "threatened or endangered species, . . . humans, domestic animals or nontarget wild animals" be reported, within three days of the incident, to a designated government agency (EPA and/or the appropriate state lead agency for regulation of pesticides). EPA requires that certified applicators of Livestock Protection Collars keep and report only those records prescribed by USE RESTRICTIONS 5 and 6.

Registrants of Livestock Protection Collar are required, by USE RESTRICTION 4 of the same typical technical bulletin, to:

". . . keep records of all collars sold or transferred at their address of record. Records shall include the name, address, state where Livestock Protection Collar certification was issued, certification number of each recipient, and dates and numbers of collars sold or transferred."

USE RESTRICTION numbers and content vary somewhat from product to product due to additional restrictions or considerations either proposed by the registrants or required by state lead agencies.

(ii) Respondent Activities

Certified Livestock Protection collar applicators are required by product labeling to prepare and maintain records of various activities associated with use and fate of Livestock Protection Collars that they purchase or obtain for use. Preparing these records consists of writing down what is done in normal use and handling of collars.

The use of predator control collars is a labor-intensive process. For a typical sheep operation, collar use involves the following activities:

- (a) corralling sheep;
- (b) isolating target flocks;
- (c) capturing appropriate livestock and equipping them with collars;
- (d) redeploying target and main flocks in ways that are expected to direct coyotes' attacks toward target flocks and away from the remainder of the producer's sheep;
- (e) inspecting target flocks weekly (or more frequently) to account for livestock alive, dead, or missing; to search for lost sheep or lost collars; to capture livestock that require adjustments to collar position or other hands-on attention; and to properly handle and dispose of irreparably damaged collars; and, when collar use is to be terminated; corralling target flocks, capturing collared livestock, removing and inspecting collars, disposing of damaged collars, and returning intact collars to proper secure storage.

The recordkeeping requirements add the need to record significant data associated with collar use such as how many collars were used, where they were used, when they were used, how many were damaged, likely causes of such damage, where collars went after use, and the occurrence of possible nontarget exposure incidents.

Registrants and/or state lead agencies have developed their own instruments that facilitate appropriate recordkeeping by certified applicators.

State lead agencies typically require certified Livestock Protection Collar applicators to

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file periodic reports summarizing collar use. Data from these reports are included in annual monitoring reports submitted to EPA by registrants or state lead agencies. Other data that appear in monitoring reports include summaries of numbers of collars sold or otherwise legally circulated in the state and the number and nature of violations detected with regard to use or handling of Livestock Protection Collars.

As with other registrants of pesticide products, Livestock Protection Collar registrants are required to file annual (confidential) production reports. These reports are required of all establishments that produce pesticides or pesticide devices in the United States, pursuant to Section 7 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

5. THE INFORMATION COLLECTED - AGENCY ACTIVITIES, COLLECTION METHODOLOGY, AND INFORMATION MANAGEMENT

5(a). Agency Activities

Reports of non-target species poisoning incidents included in the annual monitoring reports filed with EPA by state lead agencies would be reviewed by the Insecticide-Rodenticide Branch which would take whatever regulatory steps were warranted by the incident and would place a copy of the incident report in the registration file for the product involved in the incident. To date, no such incidents have been reported to EPA by state lead agencies. Reasons for this appear to be the limited extent to which collars are used, and the relatively low potential for occurrence and detection of nontarget incidents.

Livestock Protection Collar monitoring reports that registrants or state agencies must file also are reviewed by the product management team and placed in the appropriate product registration file. In addition, EPA replies directly, in writing, to the originator of the report, indicating whether the report is acceptable, whether additional details are needed for the current report or future reports, and whether any specific corrective steps are needed based upon items discussed in the monitoring report.

5(b). Collection Methodology and Management

As the number of registered Livestock Protection Collar products is very small (6 at present) and very few reports are expected to be received, no special provisions for data collection and management are needed. The reports submitted are handled and processed through mechanisms that have been developed for handling a wide variety of submissions that pertain to registered pesticide products. These include routing the submission through the routine review process, responding to the submission in writing, and filing the submission and the response in the relevant product's registration file. The processing of these submissions are tracked by EPA's Pesticide Regulatory Action Tracking (PRAT) system.

5(c). Small Entity Flexibility

Most users, including the private company that is a Livestock Protection Collar registrant, would qualify as small entities. The degree of imposition that these recordkeeping and reporting requirements impose on such individuals is minimal, considering the limited degree of latitude permitted by the Administrative Law Judge and the Administrator of the EPA, the extreme toxicity of Compound 1080, and the great potential for abuse of Livestock Protection Collars

should collars or their contents get into the hands of irresponsible persons. The main purpose of the recordkeeping requirements is to promote responsible use and handling. The main purpose for requiring monitoring reports is to establish a process through which it is mandatory to inform EPA of the results of collar use. EPA then can use the data from reports as bases for future regulatory decisions.

The mandatory submission of periodic reports from applicators to state lead agencies based on data that they are already required to collect adds only a minimal amount of burden. In the state where the Livestock Protection Collar product registered to a private firm is used, the lead agency requires the registrant to submit sales and distribution documents to the state.

5(d). Collection Schedule

As nontarget exposure incidents must be reported within three days of their occurrence there is no set schedule for collection of this information.

Livestock Protection Collar annual monitoring reports are due on a date prescribed as a condition of registration, usually February 15, for each year after the first year in which collars could be used legally.

6. ESTIMATING THE BURDEN AND COST OF THE COLLECTION

6(a). Estimating Respondent Burden

The total annual response burden associated with the use of 1080 livestock protection collars is 3,353 hours per year or 10,059 hours over a three year period. Based on monitoring of the 1080 collar reports done by the Agency, the revised estimate predicts that 75 certified applicators are expected to report each year. We estimate that no more than 75 respondents would be subject to the reporting requirements, although this figure appears to be an over-estimate because submissions reviewed during the previous three-year period indicate that the state lead agencies typically receive reports from approximately 50 applicators a year. For purposes of this ICR, however, the Agency will assume the need for 75 certified applicators to provide information in order to account for any potential increase.

The annual burden estimate for the certified applicators (estimated in Table 1) is essentially based on the previous ICR and information provided by the monitoring program. No non-target species poisonings have been reported by state lead agencies to the EPA.

The annual burden of the states and registrants (estimated in Table 2 and Table 3) was based on the previous ICR. There are currently four states that are monitoring the program and five registrants that might be required to report annually on livestock protection collar use.

Tables 1, 2, and 3 provide a breakdown of the collection activities per respondent and a

general overview of how the estimates were derived.

6(b). Estimating Respondent Costs

The total annual cost for all respondents associated with the use of 1080 livestock protection collars is estimated to be \$38,448 (Table 4). The annual cost represents a burden on certified applicators of \$21,000; a burden on states of \$14,388; and a burden on registrants of \$3,060. The annual cost for a single respondent is: certified applicator - \$280; state - \$3,597; and registrant - \$612. Note that in all but one case, the registrant is the state. Tables 1, 2, and 3 present information for estimating cost based on the burden hour estimates per respondent.

EPA has increased its estimated labor rates for registrants and State government personnel factoring in an inflation cost index of 1.056 based on the Gross Domestic Product. These labor rates are fully loaded and included benefits and overhead costs. For State agency personnel, EPA estimates labor costs of \$84, \$63, and \$32 per hour for management, technical and clerical burden, respectively. Using the Agency's burden estimates and the fully loaded labor rates, the Agency estimates State agency costs to be approximately \$ per response. The overall annual cost associated with this information collection, based on an estimate responses per year, is estimated to be \$38,448.

Table 1. Annual Certified Applicator Burden/Cost Estimates

<u>Collection Activities</u>		<u>Burden Hours</u> <u>(per year)</u>	<u>Cost</u>
		Herder (\$7/hr) ¹	
1.	Read/hear rule or any collection instrument	3	\$21
2.	Receive training ²	0	\$0
3.	Plan activities	3	\$21
4.	Create information	3	\$21
5.	Gather information	18	\$126
6.	Process and review information for accuracy	5	\$35
7.	Record, disclose, or display the information	5	\$35
8.	Store, file or maintain the information	3	\$21
	TOTAL	40	\$280

ANNUAL BURDEN: Hour Total (40) x Number of Respondents (75) = 3,000

ANNUAL COST: Cost Total (\$280) x Number of Respondents (75) = \$21,000³

¹Source: USDA, ERS. 1991, adjusted to account for inflation. Total Cash Receipts of US Sheep Production, Washington, DC 20005. Handling sheep is generally a one-person operation. Thus, the wage rate of the ranch hand is utilized for all aspects of the operation.

²The burden associated with the training is accounted for under the ICR for the Agency Certification and Training Program (EPA ICR# 0155.07; OMB Control No. 2070-0029)

³This total includes the assumption that one non-target species poisoning incident will occur and require 10 hours of burden.

Table 2. Annual State Burden/Cost Estimates

	Collection Activities	Burden Hours (per year)			Cost
		Management (\$84/hour)	Tech. (\$63/hour)	Clerical (\$32/hour)	
1	Read/hear rule or any collection instrument	0	2	0	\$126
2	Plan activities	0	10	0	\$630
3	Create information	0	15	0	\$945
4	Gather information	0	14	0	\$882
5	Process, compile, and review information for accuracy and appropriateness	0	13	0	\$819
6	Record, disclose, display or report the information	0	0	20	\$640
7	Store, file or maintain the information	0	0	3	\$96
	TOTAL	0	54	23	\$4,138

ANNUAL BURDEN: Hour Total (77) x Number of Respondents (4) = 308

ANNUAL COST: Cost Total (\$4,138) x Number of Respondents (4) = \$16,552

Table 3. Annual Registrant Burden/Cost Estimates¹

	Collection Activities	Burden Hours (per year)			Cost
		Management (\$130/hour)	Tech. (\$88/hour)	Clerical (\$40/hour)	
1	Read/hear rule or any collection instrument	0	2	0	\$176
2	Plan activities	0	1	0	\$88
3	Create information	0	0	0	\$0
4	Gather information	0	2	0	\$176
5	Process, compile, and review information for accuracy and appropriateness	0	1	0	\$88
6	Record, disclose, display or report the information	0	0	2	\$80
7	Store, file or maintain the information	0	0	1	\$40
	TOTAL	0	6	3	\$648

ANNUAL BURDEN: Hour Total (9) x Number of Respondents (5) = 45

ANNUAL COST: Cost Total (\$648) x Number of Respondents (5) = \$3,240

¹In all but one case, the registrant is the state.

6(c). Estimating Agency Burden and Cost

Based on past experience, the Agency normally estimates the annual burden to the federal government to review the submissions. The Agency's total burden associated with the 1080 livestock program has slightly increased based upon better estimates of the resources required to complete each activity and more experience in the review and oversight of the monitoring program. For this ICR, we estimate the annual burden to be 145 hours and the total annual cost to be \$10,150. As with the other areas, the Agency will incur an increase in costs due to the changes in the wage rates. These changes caused the cost burden to the Agency to increase from \$8,845, in the previous ICR, to the current \$10,150.

Annual Agency Burden/Cost Estimates

	Collection Activities	Burden Hours (annual)		Cost
		Tech. (\$70/hour) ¹	Clerical (\$33/hour) ²	
1	Develop any correspondence needed	10	0	\$700
2	Answer respondents' questions	2	0	\$140
3	Review data submissions	12	0	\$840
4	Analyze data submissions	4	0	\$280
5	Store data	1	0	\$70
	TOTAL	29	0	\$2,030

ANNUAL BURDEN: Hour Total (29) x Number of Respondents (5) = 145

ANNUAL COST: Cost Total (\$2,030) x Number of Respondents (5) = \$10,150

6(d). Table 4: Bottom Line Burden Hours and Costs/Master Table

	Total Burden Hours	Total Cost (\$)
Certified Applicator (Table 1)	3,000	\$21,000
State (Table 2)	308	\$16,552
Registrant (Table 3)	45	\$3,240
Bottom Line Respondent Total	3,353	\$40,792
Agency Total	145	\$10,150

6(e). Reasons for Change in Burden

There are no changes to the program or to the respondent responsibilities under this information collection activity. Total respondent costs associated with this program rose from

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\$38,448 to \$40,792; total agency costs rose from \$8,845 to \$10,150. Changes to total costs associated with this program are due to increased labor rates, reflecting the most current estimates.

6(f). Burden Statement

The annual respondent burden for the 1080 Livestock Collar Program is estimated to average 40 hours per certified applicator, 77 hours per state, and 9 hours per registrant participating in the program. According to the Paperwork Reduction Act, “burden” means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. For this collection, it is the time reading the regulations, planning the necessary data collection activities, conducting tests, analyzing data, generating reports and completing other required paperwork, and storing, filing, and maintaining the data. The agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection appear at the beginning and the end of this document. In addition OMB control numbers for EPA’s regulations, after initial display in the final rule, are listed in 40 CFR part 9.

Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division, U.S. Environmental Protection Agency (2822), 1200 Pennsylvania Avenue, NW, Washington, D.C. 20460. Include the OMB control number in any correspondence, but do not submit the requested information or forms to this address. The requested information should be submitted in accordance with the instructions in the Federal Register Notice seeking comment on this ICR. Please reference this document by the OMB Control No. 2070-0074 in all correspondence.